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OLA 10/014/20
10/52/01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Signature of Person Mailing Paper or Fee

Jenny LOUIE-HELM et al.

Serial No.: Unassigned

Group Art Unit: Unassigned

Filing Date: Concurrently herewith

Examiner: Unassigned

Title: FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE

FORM USING IN VITRO DISINTEGRATION TEST DATA

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Box Patent Application Washington, DC 20231

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration.

Applicants respectfully request that the Examiner review and make of record the references identified below.

Forms PTO-1449 listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

|            | U.S. PATENT DOCUMENTS |                 |  |
|------------|-----------------------|-----------------|--|
| PATENT NO. | ISSUE DATE            | PATENTEE        |  |
| 3,960,150  | 6/1/76                | Hussain et al.  |  |
| 4,695,467  | 9/22/87               | Uemura et al.   |  |
| 5,002,772  | 3/26/91               | Curatolo et al. |  |

| U.S. PATENT DOCUMENTS |            |                   |
|-----------------------|------------|-------------------|
| PATENT NO.            | ISSUE DATE | PATENTEE          |
| 5,007,790             | 4/16/91    | Shell             |
| 5,425,950             | 6/20/95    | Dandiker et al.   |
| 5,582,837             | 10/10/96   | Shell             |
| 5,635,210             | 6/3/97     | Allen, Jr. et al. |
| 5,738,874             | 4/14/98    | Conte et al.      |
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| 5,840,332             | 11/24/98   | Lerner et al.     |
| 5,861,173             | 1/19/99    | Nishioka et al.   |
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| 5,945,125             | 8/31/99    | Kim               |
| 5,972,389             | 10/26/99   | Shell et al.      |
| 6,027,748             | 2/22/00    | Conte et al.      |
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| 6,177,104             | 1/23/01    | Allen et al.      |
| 6,187,337             | 2/13/01    | Allen et al.      |
| 6,221,395             | 4/24/01    | Maggi et al.      |

## OTHER DOCUMENT

Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on in Vitro/in Vivo Correlation," Pharmaceutical Research 12(2):237-243.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As applicants are filing this Disclosure Statement at the time of filing the application, no fee is required.

Respectfully submitted,

Date Date

By:

Dianne E. Reed

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